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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,155	12/21/2000	Sylvie Rouquier	19904-008	9730

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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/747,155	ROUQUIER ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-8, 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on February 27, 2003 and the substitute specification received 12/29/03 have been entered in full.

Note: A copy of the original claims was included with the substitute specification. These claims are in conflict with those presented on February 27, 2003. It is assumed that Applicant intends the claims of February 27, 2003 to be the claims pending in the Application. Appropriate correction is required.

Withdrawn Rejections:

Applicant is notified that any outstanding rejection or objection that is not expressly maintained has been withdrawn in view of Applicant's amendments.

Maintained Rejections:

Claim Rejections - 35 USC § 112

Claims 2, 3 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 requires that the nucleic acid hybridize under stringent conditions. The term "stringent conditions" is confusing because it is a relative term and encompasses conditions of

varying degrees of stringency - such conditions determining the bounds of the claim. However, the art does not provide an unambiguous definition of the term "stringent conditions" and neither is such a definition given for the term in the specification (e.g. pg 236) which puts forth the metes and bounds of the claim Applicant is seeking protection for. It is suggested that the claim recite the actual conditions that applicant considers to be stringent, i.e., salt concentration and temperature conditions of incubations and washes.

Applicant argues that stringent conditions are clearly defined in the specification at page 236-237 (original specification). This argument has been fully considered but not deemed persuasive. The discussion about stringency at pages 236-237 is self contradictory i.e. that stringent conditions are those that allow binding only to the target sequence but to no other (lines 7-9), but are also conditions which allow binding to sequences with as little as 65% homology (lines 22-25). Further, examples are not sufficient to define the bounds of the generic term.

Claim 3 requires one or more "conservative substitutions" in a "ORX" polypeptide. The term "conservative substitution" is used in the art as a relative term and there is no art-established list of substitutions that are unambiguously considered to be conservative, and neither is such provided in the specification (e.g. page 239). Thus the metes and bounds of the claim cannot be determined.

Applicant argues that conservative substitutions are defined in the specification. This argument has been fully considered but not deemed persuasive. The discussion about conservative substitutions at pages 238-239 is self contradictory. It is stated that conservative substitutions are those in which an amino acid is replaced with an amino acid having a similar side chain. For instance, Histidine is listed as a member of the basic side chain family (charged),

but also as an aromatic and included with such a dissimilar amino acids as phenylalanine (uncharged, highly hydrophobic); thus it is unclear how similar two side chains need to be to be considered in the same family, and the discussion only defines families by way of examples.

Claims 3 and 11 are indefinite because claim 1 has been limited to a polynucleotide comprising a nucleic acid sequence of SEQ ID NO: 224; thus claims 3 and 11 specifically claim this nucleic acid but require that this nucleic acid contain variations – such would be impossible.

Claim Rejections - 35 USC § 101

Claims 1-8, 11 stand rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, as set forth in the prior Office action.

Applicant argues arguments regarding the alleged membership in the family of OXR proteins have been fully considered but not deemed persuasive. There is no single substantial utility that is commonly shared among the members of the family of OXR proteins. Any substantial utility that any one member might have would arise from specific information regarding that member, e.g. that aberrant expression correlated with a specific disease state, or that the protein bound a specific ligand. No such specific information is disclosed in the instant specification regarding the protein encoded by SEQ ID NO: 224.

Claims 1-8, 11 are also rejected under 35 U.S.C. § 112 first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know

how to use the claimed invention so that it would operate as intended without undue experimentation.

Applicants' arguments regarding the 35 U.S.C. § 112 rejection as the corollary of the 35 U.S.C. § 101 rejection have been addressed above. Further more, the potential scope of enablement rejection, argued by Applicant, would apply to claims 2, 3, 5, and 11, which claim variants of SEQ ID NO: 224.

Claim Rejections - 35 USC § 103

Claims 1-8 are rejected under 35 U.S.C. 103(a) as obvious over Freitag et al., Neuron, 15(1383-1392)1995, as set forth previously.

The specification indicates that the claimed ORX polynucleotides can be obtained by PCR amplification of genomic DNA using the primers OR3.1-OR7.1, see p 223, for example. Freitag et al. teach the amplification of genomic DNA using the primers OR3.1-OR7.1, see page 1390 col 2: PCR.

Applicant has clearly admitted on the record that all derivatives of the olfactory receptor (ORX) superfamily of nucleotides and proteins, i.e. those obtained by using PCR consensus ORX primer pairs OR5B-OR3b and OR3.1-OR7.1, are not individually distinct and independent (Paper 10, page 2); thus the instantly claimed polynucleotides cannot be patentably distinct from those disclosed by Freitag et al. At page 2 of Paper 10, Applicant states the following:

"The polypeptides and polynucleotides of the present invention are not individually distinct and independent, but are, in fact, all derivatives of the olfactory receptor (01G3

superfamily of nucleotides and proteins. As indicated on page 223, lines 3-20, the ORX genes, which are the subject of the present invention have been obtained using PCR using consensus ORX primer pairs OR5B-OR3B and OR3.l-OR7.1. The use of two pairs of consensus primers rendered the sampling representative of the ORX gene repertoire. Moreover, the homology for all the genes identified (>80%) is important in the domain between the primers. As a result of this homology, the ORX genes disclosed in the present patent application are not patentably distinct."

Applicant argues that Freitag does not suggest the human sequences but instead teach the use of frog DNA to obtain the olfactory receptors. This argument has been fully considered but not deemed persuasive. Freitag teach that comparisons between the frog receptors and corresponding mammalian receptors (particularly human) is important (e.g. see page 1386, col 2, last paragraph) and would shed further light on the structure/function relationship involved in ligand binding (e.g. see page 1390, col 1).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as obvious over Ben-Arie et al., Human Molecular Genetics 3(2)229-235, 1994.

The specification indicates that the claimed ORX polynucleotides can be obtained by PCR amplification of genomic DNA using the primers OR5B-OR3B, see p 223, for example. Ben-Arie et al. teach the amplification of genomic DNA using the primers OR5B-OR3B, see page 234, MATERIALS AND METHODS.

Again, Applicant has clearly admitted on the record that all derivatives of the olfactory receptor (ORX) superfamily of nucleotides and proteins, i.e. those obtained by using PCR

consensus ORX primer pairs OR5B-OR3b and OR3.1-OR7.1, are not individually distinct and independent (Paper 10, page 2); thus the instantly claimed polynucleotides cannot be patentably distinct from those disclosed by Ben-Arie et al.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freitag et al., Neuron, 15(1383-1392)1995 or Ben-Arie et al., Human Molecular Genetics 3(2)229-235, 1994, in view of Kiefer et al., Biochemistry 1996, 35:16077-16084.

Both Freitag et al. and Ben-Arie et al. teach the ORX polynucleotides, as discussed above regarding claims 1-8, as well as the deduced amino acid sequences of the encoded odorant receptor proteins, yet they do not teach expression of the polypeptides in host cells. Kiefer et al., teach the expression and isolation of cloned olfactory receptor proteins in host cells, see the Abstract.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, with reasonable expectation of success, to produce the encoded odorant receptor polypeptides taught by either Freitag et al. or Ben-Arie et al using the method taught by Kiefer et al.. The motivation to do so was provided by Kiefer et al. who teaches that such method is useful for the production of olfactory receptor peptides for biophysical and screening studies (see the Abstract).

Applicant's arguments regarding Freitag et al. and Ben-Arie et al. have been discussed above.

Claim Objections

Claims 3 and 11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As set for above in the rejection under 35 U.S.C. 112, second paragraph, claims 3 and 11 appear to be broader than parent claim 1, i.e. they claim the nucleic acid of claim 1 yet this nucleic acid can, at the same, time be different than that of claim 1.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (571) 272-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

March 25, 2004

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600